

APR - 9 2001

K003527

**3.0 510(k) Summary**

**SPONSOR:** Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301  
(610) 647-9700  
Contact: Thomas M. Maguire

**DEVICE NAME:** Polypin

**CLASSIFICATION:** Class II, Section 888.3030, Single/multiple component metallic bone fixation appliances and accessories.

**PREDICATE DEVICE:** Synthes (USA) Polypin

**DEVICE DESCRIPTION:** The Polypin is a 2mm diameter pin provided in a length of 35mm, which can be shortened intraoperatively to as little as 10mm. The Polypin has ring-shaped ribs to prevent the implanted pin from slipping out. It can be pushed down until it is completely below the surface of the cartilage or bone, permitting low load compression of the bone fragments. The Polypin is provided presterilized by gamma radiation and is not intended to be resterilized by the user.

**INTENDED USE:**

<u>Apical fragments:</u>	Radial head Patellar rim Navicular Metacarpal/metatarsal (proximal or distal ends)
<u>Osteochondral fragments:</u>	Talus vault Femoral condyle
<u>Cancellous/non-load bearing fragments:</u>	Talus

**MATERIAL:** Poly (L/DL-lactide)



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Thomas M. Maguire  
Project Leader, Regulatory Affairs  
Synthes (USA)  
1690 Russell Road  
P.O. Box 1766  
Paoli, Pennsylvania 19301

Re: K003527  
Trade Name: Synthes Polypin  
Regulatory Class: Class II  
Product Code: HTY  
Dated: February 5, 2001  
Received: February 7, 2001

Dear Mr. Maguire:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

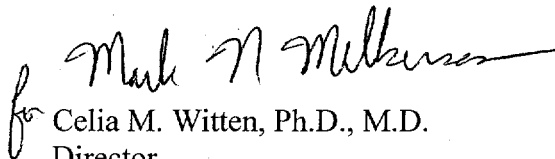
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Mr. Thomas M. Maguire

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosures



## 2.0 Indications for Use Statement

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510(k) Number (if known): K003527

Device Name: Synthes (USA) Polypin

Indications/Contraindications: The Synthes (USA) Polypin is intended for use in the fixation of small bone fragments in cases of "low load" fractures, such as apical fractures, osteochondral fragments and cancellous/non-load bearing fragments. Specific applications include the following:

Apical fragments:

Radial head  
Patellar rim  
Navicular  
Metacarpal/metatarsal (proximal or distal ends)

Osteochondral fragments:

Talus vault  
Femoral condyle

Cancellous/non-load bearing  
Fragments:

Talus

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

*for Mark A. Milburn*  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

Synthes (USA)  
Polypin 510(k)

Confidential 510(k) Number

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